

DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jody J. Neal, Co-owner
Orleans Poverty Hill Farm
13646 County House Rd.
Albion, New York 14411-9307

December 29, 2003

NYK-2004-3

Dear Mr. Neal:

On November 17, 18, 20, and 25, 2003 a U.S. Food and Drug Administration investigator conducted an inspection at your farm located in Albion, New York. This inspection confirmed that on two occasions you offered animals for sale for food that were adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused animal drugs to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a) (5) of the Act because the drugs were used in a manner that does not conform to their approved use or the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530).

On or about September 25, 2002, you offered for sale a cow identified with ear tag 21ZFW5585 for slaughter as human food. The cow was sold to and slaughtered at [REDACTED]. a. USDA analysis of tissue samples collected from that animal identified the presence of 0.08 parts per million (ppm) penicillin in kidney tissue and 9.02 ppm and 6.96 ppm sulfamethazine in liver and muscle tissues, respectively.

On or about May 12, 2003, you offered for sale a cow identified with ear tag 21ZFW5525 for slaughter as human food. The cow was sold to and slaughtered at [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 0.07 ppm penicillin in kidney tissue.

A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (21 CFR 556.510). A tolerance of 0.1 ppm has been established for residues of sulfamethazine in edible tissues of cattle (21 CFR 556.670). The presence of these drugs in excess of the established tolerances in the kidney, liver and muscle tissues of these animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Your written treatment records for veterinary drugs administered to your herd fail to identify the amount of drugs administered, the identity of the individual who administered the drugs, and the withdrawal times prior to slaughter. Foods from animals held under such conditions are adulterated under Section 402(a) (4).

You are adulterating the drug [REDACTED] brand of penicillin G procaine injectable suspension within the meaning of Section 501(a)(5) of the Act when you used the drug in an extra label manner without veterinary supervision. You used this drug in cattle at a higher than labeled dosage. Because your extra label use of [REDACTED] was not in compliance with 21 CFR Part 530, the drug is unsafe to use under Section 512(a) of the Act.

You are adulterating the drug [REDACTED] brand of sulfamethazine sustained release bolus within the meaning of Section 501(a)(5) of the Act when you used the drug in an extra label manner without veterinary supervision. The label includes the warning that this drug is indicated for calves, and not to be used on dairy cattle 20 months of age or older, whereas you used the drug to treat cows. Because your extra label use of [REDACTED] was not in compliance with 21 CFR Part 530, the drug is unsafe to use under Section 512(a) of the Act.

You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act. Likewise, the fact that you caused the adulteration of a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

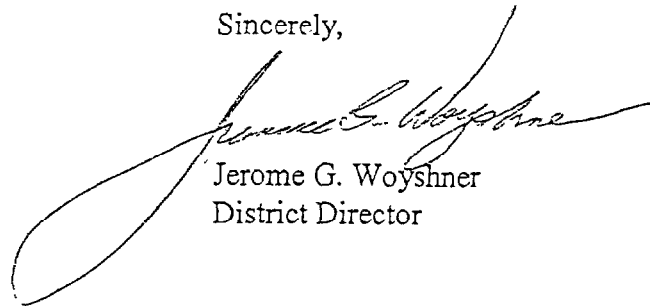
Orleans Poverty Hill Farm

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Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Laurence D. Daurio, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", is written over a large, stylized loop that extends from the left side of the signature area.

Jerome G. Woyshner
District Director

cc: Edward J. Neal & James E. Neal
Co-owners
Orleans Poverty Hill Farm
13646 County House Rd.
Albion, NY 14411-9307